

REMARKS

I. Detailed Action

A. *Specification*

1. The Examiner states that the “description of the drawings is not complete because it does not refer to all of the different drawings.” (Office Action, p. 2). The Examiner states that the description of the drawings does not refer to Fig. 1A, 2A-2C, 3A, 3B, and 4D. Applicants have amended the specification to include these Figures, thereby alleviating this objection.

2. The Examiner further states that the three tables in the specification “are not numbered consecutively.” (Office Action, p. 2). Applicants have amended the specification, numbering the tables consecutively, thereby alleviating this objection.

3. The Examiner additionally states that the “sequences identified in the specification do not always match with the sequences in the CRF or the paper copy of the sequence listing.” The Examiner further states that the “drawing include a number of sequences that are not identified with proper sequence identifiers.” (Office Action, p. 3-4). Applicants have amended the specification to include the proper sequence identifiers. Further, Applicants have also submitted a substitute sequence listing in compliance with 37 C.F.R. 1.821-1.825. Applicants have included in the substitute sequence listing the two polynucleotide sequences and one amino acid sequence of FIG. 5. Applicants submit that the sequences of FIG. 6 are present in the sequence listing as SEQ ID NOS: 11-26, and have appropriately amended the description of the drawings. Applicants submit that the substitute sequence listing includes no new matter.

II. Claim Rejections

A. 35 U.S.C. § 112, first paragraph

Claims 33, 35 and 37 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that the “new limitations of ‘selecting animals which possess a desired MC4R genotype indicative of a significantly associated phenotypic trait’ in claim 33, ‘correlated with a phenotypic trait’ in claim 35 and ‘said polymorphism being one which is associated with a phenotypic trait’ in claim 37 appear to represent new matter.” The Examiner further states that “[t]hese amendments each broaden the claims in question so as to encompass the screening for or selection of animals that have any phenotype.” (Office Action, pp. 4-5).

Applicants respectfully traverse this rejection. However, in an effort to expedite prosecution, Applicants have amended claims 33 to read “selecting pigs which possess a desired MC4R genotype indicative of a meat quality trait of pH, color, and drip loss”. Claims 35 and 37 have been similarly amended to read “meat quality trait of pH, color and drip loss”. Applicants therefore submit that claims 33, 35 and 37 are in condition for allowance.

B. 35 U.S.C. § 112, second paragraph

Claims 1, 4-10, 19, 22 and 23 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 1, and claims depending from claim 1, the Examiner states that “it is not clear what it means for an amino acid position to be ‘analogous to amino acid 298 of a

human MC4R gene product.” The Examiner further states that “[i]t would be clearer to recite that a particular codon is present, not that a change is identified.” (Office Action, p. 5).

Applicants respectfully traverse this rejection. Claim 1 reads “said polymorphism at the amino acid level is characterized as a change from an aspartic acid codon to an asparagine codon at an amino acid position corresponding to amino acid 298 of a human MC4R gene product”. The claim language therefore makes clear the particular codon which is present. However, in an effort to expedite prosecution, Applicants have amended claim 1 to omit the language “analogous to”. Applicants therefore submit that claim 1 is in condition for allowance.

With regard to claim 19 the Examiner states that “claim 19 is indefinite, because while the instant specification discloses a TaqI polymorphic site present at position 678 of instant SEQ ID NO: 1, this polymorphic site does not appear that it would be present at position 678 of the DNA amplified using instant SEQ ID NO: 5 and SEQ ID NO: 6.” (Office Action, p. 6).

Applicants respectfully traverse this rejection. In Example 1, Applicants teach that a 750 base pair portion of the porcine MC4R gene was amplified using primers SEQ ID NOS: 5 and 6. The amplification product was then subjected to TaqI digestion. A polymorphism between allele 1 and allele 2 resulting from a G to A transition at position 678 of the amplification product was revealed. Applicants therefore give a specific example in the specification where the polymorphic site is present at position 678 of the MC4R gene using the primers SEQ ID NOS: 5 and 6. Applicants therefore submit that claim 19 is in condition for allowance.

With regard to claim 22, the Examiner states that “claim 22 refers to a nucleotide that is present at ‘base 678 of the MC4R gene’ and this is indefinite because the number of a nucleotide present at a particular position is entirely dependent on the primers used to amplify the

fragment.” The Examiner further states “[t]here is no known ‘base 678 of the MC4R gene’ for all pigs or for all possible MC4R genes.” (Office Action, p. 6).

Applicants respectfully traverse this rejection. However, in an effort to expedite prosecution, Applicants have amended claim 22 to include “forward primer SEQ ID NO: 5” and “reverse primer SEQ ID NO: 6”. As stated above, Applicants provide a specific example (Example 1) in the specification where the polymorphic site is present at position 678 of the MC4R gene using the primers SEQ ID NOS: 5 and 6. Applicants therefore submit that claim 22 is in condition for allowance.

With regard to claims 23, the Examiner states that “claim 23 is further confusing because it depends from claim 22 which requires the identification of a particular restriction fragment pattern, yet claim 23 requires the identification of different patterns as representative of allele 1 and allele 2 of the MC4R gene.” (Office Action, p. 7)

Applicants have amended claim 23 to depend from independent claim 20. Applicants have also amended claim 23 to include “forward primer SEQ ID NO: 9” and “reverse primer SEQ ID NO: 10. Applicants therefore submit that claim 23 is in condition for allowance.

C. 35 U.S.C. § 112, first paragraph: Enablement

Claims 1, 4, 10, 19-24, 29-37, and 40 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which does not meet the enablement requirement. The Examiner states that the specification “does not reasonably provide enablement for methods which screen other species of animals, or methods which utilize drawn conclusions based on nucleotide(s) present at positions other than 678 of SEQ ID NO: 1, or methods which identify pigs that would produce meat with any other relative meat qualities or methods which identify/screen for any animal having any possible phenotypic trait”. (Office Action, p. 7). The

Examiner further states that “claims which rely on ‘linked markers’ and specifically claim 31 which mentions these markers in particular, the guidance in the specification is not sufficient to use these markers in any assay for detection of traits”. (Office Action, p. 9).

Applicants respectfully traverse this rejection. However, in an effort to expedite prosecution, Applicants have amended independent claims 1, 20, 29, 30, 32-37, and 40. The Examiner notes that the specification is “enabling for methods for identifying a pig which possesses a genotype indicative increase pH, decreased Minolta, decreased drip loss, or increased rate of weight gain, wherein a pig homozygous for adenine at position 678 of SEQ ID NO: 1 is indicative of said pig being more likely to have the phenotype than a pig with a guanine at position 678 of SEQ ID No: 1”. (Office Action, p. 7). As amended, each of the independent claims recites “pigs” and the traits or characteristics “pH, color, and drip loss”. Claim 1 now requires that the polymorphism is “characterized as a change from as aspartic acid codon to an asparagine codon at an amino acid position corresponding to amino acid 298 of a human MC4R gene product”. Claim 20, 29, 30, 32-37 and 40 have also been amended to recite “nucleotide substitution at position 678 of the MC4R gene as set forth in SEQ ID NO: 1”, “nucleotide substitution at position 678 of SEQ ID NO: 1”, or “G to A point mutation at position 678 of SEQ ID NO: 1”.

The Specification is fully enabling for the claimed methods. Applicants teach that variation in the MC4R gene is associated with desired meat quality characteristics. The Specification identifies a specific polymorphism that exists within the MC4R gene which allows one skilled in the art to select those pigs which are likely to produce these desired traits (Specification, pp. 7-10, 13-26).

As the specification teaches, the initial step in identifying the presence of the polymorphism involves isolating and assaying an animal's DNA for the presence of variation using techniques well known in the art. (Specification, pp. 8-13). The Specification provides a specific example of isolating and identifying a polymorphism within the MC4R gene at pages 13-16.

Once the presence of a polymorphism within the MC4R gene has been identified, the specification teaches the association of that polymorphism with favorable meat quality characteristics. An example of an association study is provided in the specification. See pages 16-26. Accordingly, one of skill in the art would be able to practice Applicants' invention without undue experimentation.

Further, with respect to the Examiner's argument that there is insufficient guidance in the specification for the claims which recite "linked markers", the Specification teaches that by establishing a linkage between alternative DNA markers and DNA markers known to be associated with the MC4R gene which have been shown to be associated with the desired meat quality characteristics, it is possible to indirectly select for the polymorphism with these alternative DNA markers. (Specification, p. 12) The Specification teaches the MC4R gene is significantly linked to several markers on porcine chromosome 1. (Specification, pp. 15-16; Figures 4a-4d). Further, the specification teaches that markers "may be identified using any method known to one of ordinary skill in the art which identifies the presence of absence of a particular marker". (Specification, p. 10). The Specification also gives a specific example in Example 3 of associating marker genotype with the phenotype of desired meat quality characteristics. (Specification, Example 3, pp. 20-24). Accordingly, the specification is enabling for the use of "linked markers" in association with the present invention. Further, and

in an effort to expedite prosecution, Applicants have amended claims 30 and 31 to recite “pigs” and also the meat quality traits of “pH, color and drip loss”.

In light of the above remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 1, 4, 10, 19-24, 29-37, and 40 under 35 U.S.C. § 112, first paragraph.

D. 35 U.S.C. § 112, first paragraph: Written Description

Claims 1, 4-10, 19-24, 29-37, and 40 stand rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that “the claims are broadly drawn to methods comprising the analysis nucleic acids that are indicative of these phenotypes and encompass the use of a multitude of different nucleic acid molecules of a wide variety of unique sequences.” (Office Action, p. 16). The Examiner further states that the specification “does not provide any polymorphisms other than the aforementioned polymorphisms as associated with any particular meat characteristic or phenotype in general.” (Office Action, p. 17).

Applicants respectfully traverse this rejection. The Examiner is implicitly requiring that Applicants disclose each member of the claimed genus. This is contrary to the written description requirement. The Federal Circuit has stated that a genus claim may be adequately described where there is a "recitation of structural features common to the members of the genus." *Regents of University of California v. Eli Lilly*, 119 F.3d 1550, 1569 (Fed. Cir. 1997). Moreover, the USPTO's Written Description Guidelines states that a sufficient variety of species has been described to reflect variation within the genus where "one of skill in the art would

recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the member of the genus in view of the species disclosed."

Applicants' claimed invention relates to the association of the MC4R gene to the phenotypic traits of meat quality characteristics including pH, color, and drip loss. Thus, each species within the genus encompassed by Applicants' claims all share the common attribute of being a quantitative trait loci that has a measurable effect on these phenotypic traits.

In order to expedite prosecution, Applicants have amended independent claims 1, 20, 29, 30, 32-37, and 40. The Examiner notes that "the specification also teaches an analysis of a single polymorphism in this gene [porcine MC4R gene (instant SEQ ID NO: 1), with the polymorphic site being located at position 678 of SEQ ID NO: 1". (Office Action, p. 17). As amended, each of the independent claims now recites "pigs" and the traits or characteristics "pH, color, and drip loss". Claim 1 now requires that the polymorphism is "characterized as a change from aspartic acid codon to an asparagine codon at an amino acid position corresponding to amino acid 298 of a human MC4R gene product". Claim 20, 29, 30, 32-37 and 40 have also been amended to recite "nucleotide substitution at position 678 of the MC4R gene as set forth in SEQ ID NO: 1", "nucleotide substitution at position 678 of SEQ ID NO: 1", or "G to A point mutation at position 678 of SEQ ID NO: 1".

The structural feature common to all members of the genus is the MC4R gene. Further, in order to fall within the scope of Applicants invention, the variant screened for within the MC4R gene, or a region therein, must have the function of being associated with the meat quality characteristics of pH, color, and drip loss. The specification teaches at least one polymorphism that has been identified which correlates with a phenotypic difference in the meat quality characteristics of pH, color, and drip loss. This polymorphism is identified in the specification

using the restriction enzyme *TaqI*, and by a nucleotide substitution in the MC4R gene. See specification, Examples 1-4, pages 13-26. One of skill in the art would recognize that Appellant's were in possession of the common attribute within the genus, i.e., the association between the MC4R gene and the meat quality characteristics of pH, color, and drip loss, Applicants have adequately described a representative number of species.

In light of the above remarks and amendments, Applicants respectfully request reconsideration and withdrawal of the rejections to claims 1, 4-10, 19-24, 29-37, and 40 under 35 U.S.C. § 112, first paragraph.

E. 35 U.S.C. § 102(a)

Claims 1, 4-10, 19, 30, 31, 33, 35, 36, 37, and 40 stands rejected under 35 U.S.C. § 102(a) as being anticipated by Rothschild et al (WO 00/06777). The Examiner states Rothschild teaches "a method for identifying a pig which possesses a genotype indicative of increased fat content, said method comprising obtaining a nucleic acid sample from said animal and assaying for the presence of a G → A polymorphism at position 678 of instant SEQ ID NO:1". (Office Action, p. 19). The Examiner further states that "Rothschild et al. teach that animals homozygous for allele 1 had on average less back fat than those homozygous for allele 2" and that "higher back fat . . . is considered 'favorable' meat quality".

Applicants respectfully traverse this rejection. Applicants have amended independent claims 1, 30, 33-37, and 40 to recite "meat quality characteristics of pH, color, and drip loss", "meat quality trait of pH, color, and drip loss", or "meat quality characteristics selected from the group consisting of pH, color, and drip loss." Rothschild et al. (WO 00/06777) teaches the association of a polymorphism in the MC4R gene with the phenotypic trait of higher back fat. Rothschild et al. (WO 00/06777) does not teach the identification of polymorphism in the MC4R

gene with the phenotypic trait of meat quality characteristics of pH, color, and drip loss.

Accordingly, Rothschild et al. (WO 00/06777) can not anticipate claims 1, 4-10, 19, 30, 31, 33, 35, 36, 37, and 40. Applicants therefore respectfully request reconsideration and withdrawal of the rejection to claims 1, 4-10, 19, 30, 31, 33, 35, 36, 37, and 40 under 35 U.S.C. § 102(a) as being anticipated by Rothschild et al. (WO 00/06777).

F. Non-statutory Double Patenting Rejection: U.S. Patent No. 6, 803,190

Claims 1, 4-10, 19, 20-24, 29, 32-37, and 40 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,203,190. The Examiner states “although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued patent anticipate the instantly claimed invention.” The Examiner further states that “the issued claims render obvious the claimed invention.”

Applicants respectfully traverse on the basis that the claims are patentably distinct. Claims 1-11 of U.S. Patent No. 6,203,190 do not teach, or render obvious, all the elements of the present invention. Independent claims 1, 20, 29, 30, 32-36, and 40 have been amended to recite “meat quality characteristics of pH, color, and drip loss”, “meat quality trait of pH, color, and drip loss”, or “meat quality characteristics selected from the group consisting of pH, color, and drip loss.”.

In contrast, claims 1-11 of U.S. Patent No. 6,203,190 are directed towards the association of a polymorphism in the MC4R gene with the phenotypic traits of less back fat, lower daily gain, and lower feed intake, leanness, and faster rate of gain. The Specification of the present application teaches that the discovery of the association between the polymorphism present in the

MC4R gene and the phenotypic traits of pH, color, and drip loss was unexpected given the previous association between the polymorphism and growth rate:

In the earlier application this site was found to significantly correlate with weight gain and feed intake, in other words, traits involving growth rate of the pig. Surprisingly, as fast growth is generally considered to be negatively correlated with meat quality, the marker has now been shown to correlate with favorable meat characteristics such as pH level, marbling, color, and drip loss. (Specification, p. 5).

Claims 1-11 of U.S. Patent No. 6,203,190 are not directed towards the identification of polymorphism in the MC4R gene with the phenotypic trait of meat quality characteristics of pH, color, and drip loss. Further, the inventions of present claims 1, 4-10, 19, 20-24, 29, 32-37, and 40 are not rendered obvious by claims 1-11 of U.S. Patent No. 6,203,190. Accordingly, Applicants respectfully request that since the references do not teach or suggest all the limitations of the claims that this rejection be withdrawn. Applicants respectfully submit that claims 1, 4-10, 19, 20-24, 29, 32-37, and 40 are in a form for immediate allowance.

G. Non-statutory Double Patenting Rejection: Application No. 10/834,485

Claims 1, 4-10, 19, 30, 31, 33, 35-37, and 40 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 20-23, and 28-32 of Application No. 10/834,485. The Examiner states “although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate or make obvious the instantly claimed invention.”

Applicants respectfully traverse on the basis that the claims are patentably distinct. Claims 1-11, 20-23, and 28-32 of Application No. 10/834,485 do not teach, or render obvious, all the elements of the present invention. Independent claims 1, 30, 33, 35-37, and 40 have been amended to recite “meat quality characteristics of pH, color, and drip loss”, “meat quality trait of

pH, color, and drip loss”, or “meat quality characteristics selected from the group consisting of pH, color, and drip loss.”

In contrast, claims 1-11, 20-23, and 28-32 of Application No. 10/834,485 are directed towards the association of a polymorphism in the MC4R gene with the phenotypic traits of fat content, growth rate, and feed consumption. As stated above, the Specification of the present application teaches that the discovery of the association between the polymorphism present in the MC4R gene and the phenotypic traits of pH, color, and drip loss was unexpected given the previous association between the polymorphism and growth rate. (Specification, p. 5).

Claims 1-11, 20-23, and 28-32 of Application No. 10/834,485 are not directed towards the identification of polymorphism in the MC4R gene with the phenotypic trait of meat quality characteristics of pH, color, and drip loss. Further, the inventions of present claims 1, 4-10, 19, 20-24, 29, 32-37, and 40 are not rendered obvious by claims 1-11 of U.S. Patent No. 6,203,190. Accordingly, Applicants respectfully request that since the references do not teach or suggest all the limitations of the claims that this rejection be withdrawn. Applicants respectfully submit that claims 1, 4-10, 19, 30, 31, 33, 35-37, and 40 are in a form for immediate allowance.

III. Conclusion

In light of the above remarks, Applicants respectfully assert that claims 1, 4-10, 19-37 and 40 are now in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the above rejections. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees are believed to be due in connection with this amendment; however, consider this a request for any inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. A. Hodgson', with a horizontal line extending to the right.

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Enclosure: Sequence Listing